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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,022	02/09/2004	Ramez Emile Necola Shehada	064693-0101	9082

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EXAMINER

HILL, LAURA C

ART UNIT PAPER NUMBER

3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/776,022

Applicant(s)

NECOLA SHEHADA ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-16 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-16, 22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 November 2006 has been entered.

Election/Restrictions

2. Applicant's election without traverse of species I (claims 21 and 22) in the reply filed on 22 January 2007 is acknowledged. However, this response to the election/restriction requirement dated 30 November 2006 is incomplete. On page 2 of this election requirement, Examiner intended Applicant to pick one claim from the embodiment of species I (claim 21 or claim 22) and *in addition* to pick one claim from the embodiment of species II (claim 23 or claim 24). In response to this error pointed out to Marc Brown in a telephone interview on 5 February 2007, Applicant elected claims 22 and claim 24 from each of species I and species II without traverse on 6 February 2007. Thus claims 1-4, 6-16, 22, and 24-26 are hereby examined on the merits.

Response to Arguments

3. Applicant's arguments with respect to claims 1-4, 7-16 and 21-24 over Skrabal/Goodman and claim 6 over Skrabal, Goodman, Koehn, Santomieri, and Beck

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(see Remarks pages 8-12 dated 8 November 2006) have been considered but are moot in view of the new ground(s) of rejection as discussed below.

Claim Objections

4. All objections to the claims have been removed in view of Applicant's remarks and amendments submitted 8 November 2006.

Claim Rejections - 35 USC § 112

5. All rejections to the claims under 35 USC 112, 1st paragraph have been removed in view of Applicant's remarks and amendments submitted 8 November 2006.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-4, 6-9, 10-16, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599) in view of Russo et al. (US 4,317,452). In regard to claims 1, 3-4, 12, 15-16 Johnson discloses an implantable surgical drain 1 comprising an elongated conduit 2 configured to be implanted in and to drain from a body cavity (column 1, lines 7-10, column 2, lines 12-28); the drain further comprises a first optical fiber/sensing element 11, 21, 27, a second optical fiber 11, 21, 27, and a third optical fiber 11, 21, 27 for sensing a different physiological property such as blood pressure (column 1, lines 44-50), the first and second fibers disposed at different locations to sense the same physiological property such as oxygenation (column 2, lines 62-66, figure 2); the fibers are configured to transmit and receive energy from body tissue (column 1, lines 20-25 and lines 44-49, column 2, lines 12-22 and lines 51-66).

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Johnson further discloses the distal ends of the optical fibers are configured for insertion into tissue (column 2, lines 29-50). Johnson does not expressly disclose the conduit comprises a plurality of holes spaced along substantially the entire length of the drain portion. **Russo** discloses a surgical drain comprising an implantable conduit 10 (column 3, lines 26-30) having a plurality of holes along substantially the entire length of the drain portion which allows body fluids in the cavity to pass into and along the conduit into a drainage site (figure 1, column 2, lines 7-19, column 4, line 56-column 5, line 2). One would be motivated to modify Johnson with the plurality of holes as taught by Russo to affect the manner in which fluid passes and flows into the tube since the references are in the same field of endeavor; implantable conduits. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheters thus providing drainage holes.

In regard to claim 2 Johnson further discloses that the drain comprising a sensing system that can sense physiological properties, including oxygenation and pressure (column 1, lines 44-49, column 2, lines 16-22 and 33-36).

In regard to claims 6 and 14 Johnson discloses the fibers embedded within the conduit (all figures, columns 3, lines 6-9).

In regard to claims 7-9 and 11 see the discussion above with respect to claim 1. Johnson further discloses the drain further comprises an oximeter that receives energy from the optical fibers 11,21, 27 (column 2, line 62-column 3, line 5). The oximeter provides measurements so it would inherently have to process and display these measurements in some form to the user. The discovery of a previously unappreciated

property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not expressly disclose not render the old composition patentably new to the discoverer. *Atlas Powder Co. v. Ireco Inc.*, 190F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In regard to claim 10 Johnson discloses third sensing element as discussed above with respect to claim 1. Johnson further discloses additional fiber optics 60 (column 4, lines 47-50).

In regard to claim 13 Johnson discloses the optical fibers 11, 21, 27 includes a component such as a surface or a distal end of any other portion of the fiber itself affixed to conduit 2 (figures 2-6, column 3, lines 6-9).

In regard to claim 24 Johnson discloses first and second fiber optics located on opposing surfaces of the elongated conduit (figures 2, 3, 7).

In regard to claim 25 see the discussion above with respect to claim 1.

In regard to claim 26 see the discussion above with respect to claims 1 and 7.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 3,866,599) in view of Russo et al. (US 4,317,452) as applied to claim 1, and further in view of Combs et al. (US 6,280,703). Johnson/Russo disclose the sensing drainage device as discussed above with respect to claim 1. Johnson/Russo do not expressly disclose the tissues are not part of the same organ. **Combs** discloses a method of simultaneously measuring physiological functions of multiple groups of body cells using

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2 or more emitting tracers (column 4, lines 8-13) such as fiber optic sensors (column 7, lines 55-67, column 8, lines 33-36) to reduce the risk of fatality due to multiple organ failure (column 3, lines 58-60). One would be motivated to modify the sensing device of Johnson/Russo to be used in a plurality of different organs to risk patient fatality since the references are in the same field of endeavor; devices that measure physiological parameters using fiber optics. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device, thus providing two tissues that are not part of the same organ.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Polanyi (US 3,674,013) teaches a fiber optic catheter 10 implanted into the body with light emitting and light receiving optical fibers 18, said fibers 18 are directed at an angle to one side of the catheter wall so that the optical fiber remains spaced from the body organs and as a result, this reduces the chance of unreliable or false readings from the body organ or cavity. Fonger et al. (US 5,291,896) discloses a cardiac probe attached to the pulmonary artery and having drainage openings 44. Mann et al. (US 6,809,653) discloses a sensing probe 10, processor, transmitter 100, and displaying monitor 200 for determining physiological properties such as glucose, oxygen saturation, and also resting against a tissue.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill

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Examiner
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LCH

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TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

Tatyana